



November 16, 2007

BY E-MAIL and U.S. MAIL

Carol J. Monahan-Cummings
Chief Counsel
Office of Environmental Health Hazard Assessment
1001 "I" Street, MS#25B
Sacramento, CA 95816

Re: Proposition 65 Regulatory Update

Dear Ms. Monahan-Cummings:

This letter provides comments on the above-referenced regulatory update. These comments are made on behalf of the Mateel Environmental Justice Foundation, Californians for Alternatives to Toxics, and the Ecological Rights Foundation. It is difficult to provide comments on the proposed Regulatory Update because what has been proposed is so amorphous. Mateel requests that stakeholders have a further opportunity to provide more specific comments about proposed regulatory changes when and if there is more specific information about what is likely to be proposed.

Regarding any regulation or regulations which provide definitions for statutory terms, it would be helpful if the current definition provided for "knowingly" to be expanded or clarified to make clear that "knowledge" is something separate from "belief." For example, knowledge should include knowledge gained as a result of the receipt of a 60 Day Notice. This is consistent with the Final Statement of Reasons for various regulations, including, 22 CCR 12201(c) (now renumbered as 12102(n)) and 22 CAR 12903. It would also be helpful if "intentionally" were expressly defined to mean, among other things, intentionally putting an item into California's stream of commerce when the person in the course of doing business knows that normally intended use of the product will result in an exposure to a listed chemical.

With regard to addressing averaging issues related to exposures to listed chemicals: As to average exposure levels, the California Court of Appeal addressed this issue in the recent *Bond* case and we fail to see a need to change what the Court of Appeal decided there. As for averaging a large exposure that occurs on one day or several days over the course of an entire lifetime or period of gestation, that kind of averaging may or may not be appropriate given the mechanism by which a particular chemical causes cancer/reproductive toxicity. For some

chemicals averaging short-term exposures over a lifetime may be appropriate; for other chemicals such an approach would not be appropriate. For example, for pre-natal exposures to some endocrine disrupting chemicals such as dioxin, the timing of the exposure is more important than either the dose or duration. Any regulation that pertained to this kind of averaging would need to take account of the various mechanisms for carcinogenesis and/or reproductive toxicity and should only be allowed where it is clearly that mechanism makes such averaging appropriate. Needless to say, any regulatory conclusions OEHHA makes about such issues must be supported by the same level of scientific rigor that is required for the listing of a chemical as known to cause cancer and/or reproductive toxicity. One thing should be made clear via regulation – that there is no connection between ANY averaging that might occur and the no significant risk levels set at section 12705 and the MADL levels set at section 12805. It should be made clear that if the actual exposure does not rise to the safe harbor level ON A PARTICULAR DAY then the exposure is deemed not to be significant. Conversely, it should be made clear that a high level exposure on a particular day or days, *cannot* be averaged over an entire lifetime (or a pregnancy) and then that average daily level compared to the safe harbor level so as then to determine that there was no actionable exposure on ANY day, even those days when the actual exposure was above the safe-harbor level.

With regard to the item: “Address scientific issues concerning methods of detection and analysis and detection limits”, we believe the current version of section 12900 needs only minor tinkering. The regulation should be amended to make it clear that where a permit allows an alleged violator to use several methods of detection, then the most sensitive method of detection allowed under the permit must be the one the alleged violator used if the alleged violator is to rely on the affirmative defense provided by section 12900. The regulation should also be amended to make it clear that if an alleged violator conducts a proper test for a chemical in a specific medium and there is no detection, then it shall be presumed that there is no discharge, release or exposure via *that specific medium*. With regard to consumer products, these products change over time and can often be reformulated. In other words, the specific unit of product tested may have been reformulated so as not to contain the chemical at issue while, at the same time, other, earlier (or later) produced units of the same product do indeed contain the chemical at issue. The regulation should thus be amended to make it clear that a properly conducted test requires that the unit(s) tested must be representative of the product(s) for which the affirmative defense is to be asserted.

With regard to the item: “Adopt NSRLs and MADLs for important common chemicals”, we believe the MADL for lead and lead compounds should be revisited. Some years ago, Dr. Donald provided a declaration in which he pointed out how unscientific the process was by which DHS determined the 0.5 microgram per day MADL for lead. Moreover, recent research shows that lead has developmental effects at levels much lower than was thought at the time DHS originally set the MADL for lead. For example, the California Air Resources Board has

found that there is ***no threshold*** below which there is a no observable effect for the developmental effects of lead.

With regard to the item concerned with amending warning regulations, these regulations should be changed to make it clear that for consumer products, a warning must be provided before purchase of the product that causes the exposure. For environmental exposures, it should be made clear that warnings must be given before an exposure occurs. For occupational exposures, OEHHA should delete the current 22 Cal. Code Regs. § 12601(c)(3), which allows an employer to post a meaningless, “Warning this area contains a chemical known to cause cancer” sign in the workplace. Since the warnings required under section 25249.6 are for exposures to a chemical, section 12601 should be amended to require that warnings inform people that they are being ***exposed*** to a chemical known to cause cancer and/or birth defects. This may be accomplished with the traditional “this product contains” language if the warning is on a food item or something that a person puts into his or her body. But for many consumer products, telling the consumer that the product contains a chemical does not inform the person that the person will be exposed to the chemical.

With regard to clarifying the relative level of responsibility for providing warnings between manufacturers, distributors and retailers for various types of exposures: It is unclear how this can be done other than to emphasize that every “person” in the chain of distribution of the product is responsible for providing a warning to the extent that “person” knows that the product will cause an exposure. If a manufacturer or importer has sold a product to a retailer and the retailer doesn’t know the product causes an exposure, then the retailer should not be held accountable for ***exposures*** that occur ***before*** the retailer gains knowledge of the exposure. But if a retailer knows that a product causes an exposure and knows that the product bears no warning, it would provide a perverse incentive to exempt the retailer from responsibility for providing a warning. No retailer is required to sell products that violate Proposition 65. If the retailer obtains a product that will cause a Proposition 65 exposure, if the manufacturer or importer did not provide a warning for the product, and if the retailer does not want to be responsible for providing a warning, then the appropriate response for the retailer is to ***send the product back or refuse to sell it.***

With regard to clarifying issues relating to assessing the level of exposure to listed chemicals from consumer products (i.e. transfer factors), we understand the appeal of such a regulation. But please consider and incorporate by reference Mateel’s comments to OEHHA’s proposal to issue an interpretive guideline for hand-to-mouth transfer factors for lead from fishing tackle. Any attempt to formulate such a regulation should conform to the same standards for scientific rigor that are required for OEHHA to list a chemical as known to causes cancer or reproductive toxicity. This means for each exposure scenario that OEHHA attempts to address, there must be pertinent, valid, and on-point empirical studies that support any conclusions OEHHA makes about a specific transfer factor. Any other approach would make it appear that

OEHHA wields the concept of “scientific rigor” as a partisan weapon, requiring great scientific rigor and support for any listing or regulation opposed by the business community, while applying junk science to support regulations that community favors. Please keep in mind the words of the preamble to Proposition 65.

With regard to the potential for developing a regulation addressing exposures to beneficial nutrients in foods, there is no basis in the law as passed by the voters for exempting from the warning requirement chemicals that cause cancer/reproductive toxicity but that are also beneficial in food. If there are beneficial levels of exposure to these chemicals and exposure at these beneficial levels does not cause cancer or reproductive toxicity at those levels, then the proper way to deal with this issue is to provide a safe harbor level for exposure that does not cause cancer assuming a lifetime of exposure at the level in question and/or no observable effect at 1000 times the level of exposure in question.

We believe OEHHA should make a regulation or regulations that take body burden into account when assessing the significance of an exposure. For example, the half-life for polychlorinated dibenzo dioxins and furans in the human body is approximately seven years. This means that for a dioxin exposure that a person experienced seven years ago, fully one-half of that dioxin is still carried in that person’s adipose tissue. Similarly, the half life for lead in the blood of adults is up to 25 days and in children can be as long as 8 to 12 months. Research on some chemicals, such as dioxins, also show that it is total body burden of the chemical – and not necessarily a particular exposure on a particular day – that are responsible for many of the ways by which dioxin causes developmental toxicity. This concept should be incorporated into the regulations at several levels. As to exposure as defined in section 12102(i), this definition should be amended to make it clear that exposure includes body burden of the chemical in question. As to the level of exposure as described in sections 12721 and 12821, these regulations should be amended to make it clear that the “exposure in question” includes that part of the exposed person’s body burden for which the person doing business is responsible. Finally, as to the significance of an exposure as determined in sections 12701-12705 and 12801-12805 those regulations should be amended to make it so the significance of an exposure “for which the person doing business is responsible” is determined while considering that exposure in light of the average body burden to the chemical from all sources that the exposed person bears. This concept should apply both in setting the NSRL and/or MADL and it should be made clear that the significance of any daily exposure is judged in light of how toxic the total body burden of the chemical the exposed person bears. Obviously, this would only be appropriate where an average body burden could be established and would also only be relevant as to chemicals for which a person’s body burden is relevant to the mechanism of carcinogenesis and/or reproductive toxicity.

Finally, we believe that section 12903 should be amended to allow citizens to provide public bodies – the Attorney General, District Attorneys and City Attorneys – with notice of

Carol J. Monahan-Cummings

November 16, 2007

Page 5

violation via e-mail or other electronic means. This could mean providing the notice electronically to the Attorney General which would then distribute the notice electronically and automatically to each of the relevant District and City Attorneys. It could also mean allowing notice to be sent by e-mail to those public bodies that have e-mail addresses.

Cordially,

William Verick